

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Annie BARDAT et al.

Application No.: 10/563,620

Confirmation No.: 1914

Filed: June 19, 2006

Art Unit: 1656

For: METHOD FOR STABILIZING A  
CRYOPRECIPITATE OF PLASMATIC  
PROTEINS FOR BEING SUBJECTED TO A  
VIRAL INACTIVATION THERMAL  
TREATMENT

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Examiner: H. A. Robinson

**INFORMATION DISCLOSURE STATEMENT**  
**(SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL**  
**REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE**  
**1.114 RCE APPLICATION)**

MS Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

II. COPIES

☒ a. Copies of cited U.S. patents and patent application publications are not included. Copies of foreign patent documents and non-patent literature are included.

☐ b. Some or all of the documents listed on the PTO-SB08 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

☐ c. REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Appl. No(s) and U.S. Filing Date

PCT/FR2004/001788 filed July 8, 2004

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

☒ a. DOCUMENTS IN THE ENGLISH LANGUAGE - The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.

☒ b. DOCUMENTS NOT IN THE ENGLISH LANGUAGE - A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows: English Abstract provided for EP 0 359 593.

☒ c. ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

☒ d. OTHER - The following additional information is provided for the Examiner's consideration. International Search Report dated December 03, 2004, for PCT/FR2004/001788.

IV. FEES (check one box)

☐ a. This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required.

☐ b. This Information Disclosure Statement is being filed concurrent with the filing of a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required.

☐ c. This Information Disclosure Statement is being filed within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. *(This section is not to be used with RCE's.)*

☐ d. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.

☐ e. This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.

☒ f. This Information Disclosure Statement is being filed before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). **No fee or statement is required.** In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p).

☐ g. This Information Disclosure Statement is being filed before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

☐ No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached.  
or

☐ See the statement below. No fee is required.

V. STATEMENT UNDER 37 C.F.R. § 1.97(e)

(check only one box)

The undersigned hereby states that:

☐ a. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or

☐ b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ c. No item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.

☐ d. Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VI. PAYMENT OF FEES (check one box)

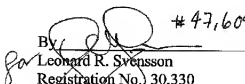
- ☐ The required fee is listed on the attached Fee Transmittal.
- ☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: November 14, 2006

Respectfully submitted,

By:  #47,604  
Leonard R. Svensson  
Registration No. 30,330  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
12770 High Bluff Drive  
Suite 260  
San Diego, California 92130  
(858) 792-8855  
Attorney for Applicant

Attachment(s):

- ☒ PTO-SB08
- ☒ Documents
- ☒ International Search Report
- ☐ Fee
- ☐ Other:

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449/PTO		<b>Complete if Known</b>			
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)		Application Number	10/563,620-Conf. #1914		
		Filing Date	June 19, 2006		
		First Named Inventor	Annie BARDAT		
		Art Unit	1656		
		Examiner Name	H. A. Robinson		
Sheet	1	of	2	Attorney Docket Number	1217-0173PUS1

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No.	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/H.A.R.	AA*	US-4,650,678-A	03-17-1987	Burk Wolfgang et al	
	AB*	US-2001/049361-A1	12-06-2001	Yamashita Chikamasa et al	
	AC*	US-4,992,419-A	02-12-1991	Gruber Werner et al.	
	AD*	US-5,919,443-A	07-06-1999	Michaelis Uwe et al	
	AE*	US-5,831,027-A	11-03-1998	Mcintosh Ronald Vance et al	
	AF*	US-5,399,670-A	03-21-1995	Bhattacharya Prabir et al	
	AG*	US-4,470,968-A	09-11-1984	Paul K et al	
V	AH*	US-4,623,717-A	11-18-1986	Fernandes Peter M et al	
	AI*	US-6,623,717-B2	11-21-2002	Angalah et al.	

FOREIGN PATENT DOCUMENTS					
Examiner Initials	Cite No.	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
/H.A.R.	BA	WO/99/10011-A1	03-04-1999		
	BB	EP-1197221-A	04-17-2002		
/H.A.R.	BC	CA-1260389	09-26-1989	Levy Jay A et al.	
/H.A.R.	BD	EP-0094611-A2	11-23-1983	Cedars Sinai Medical Center	
/H.A.R.	BE	EP-0359593-A1	03-21-1990	Centre Regional De Transfusion	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \* CITE NO.: Those applications which are marked with an asterisk (\*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(ii)) because that application was filed after June 30, 2003 or is available in the IFW. \* Applicant's unique citation designation number (optional). \* See Kind Code of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. \* Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). \* For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. \* Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. \* Applicant to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>6</sup>
/H.A.R.	CA	Winkelman L et al., "Severe Heat Treatment of Lyophilised Coagulation Factors", Current Studies in Hematology and Blood Transfusion, Karger, Basel, OH, no. 56, 1989, pages 55-69			
/H.A.R.	CB	Margolis J et al., "Stabilising Effect of Aminoacids on Factor VIII In Lyophilised Cryoprecipitate", Lancet The, Lancet Limited, London, GB, 8 December 1984, page 1345			
/H.A.R.	CC	Kyte J et al., "A Simple Method for Displaying The Hydrophobic Character of A Protein", Journal of Molecular Biology, London, GB, vol. 157, no. 1, 5 May 1982, pages 105-132			
/H.A.R.	CD	Jay A. LEVY et al., "Inactivation by Wet and Dry Heat of AIDS-Associated Retroviruses During Factor VIII Purification from Plasma," The Lancet, June 22, 1985, Pgs. 1456-1457.			
/H.A.R.	CE	Duncan P. THOMAS, "Annotation: Reducing the risk of virus transmission by blood products," British Journal of Haematology, 1988, Vol. 70, Pgs. 393-395.			
/H.A.R.	CF	S. J. SKIDMORE et al., "Serological Evidence That Dry Heating of Clotting Factor Concentrates Prevents Transmission of Non-A, Non-B Hepatitis," Journal of Medical Virology, 1990, Vol. 30, Pgs. 50-52.			
Examiner Signature	/Hope Robinson/			Date Considered	12/22/2008

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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		Art Unit	1656
		Examiner Name	H. A. Robinson
		Attorney Docket Number	1217-0173PUS1
Sheet	2	of	2

/H.A.	CG	N. Heimbürger et al., "Strategies to Produce Virus-Safe Blood Derivatives," Morgenthaler J-J (ed): Virus Inactivation in Plasma Products. Curr Stud Hematol Blood Transfus, Basel, Karger, 1989, Vol. 56, Pgs. 23-33.	
/H.A.	CH	M. Wickerhauser et al., "Development of Large-Scale Fractionation Methods: VI An Improved Method for Preparation of Antihemophilic Factor," Vox Sang., 1978, Vol. 35, Pgs. 18-31.	
/H.A.	CL	P. KISTLER et al., "Large Scale Production of Human Plasma Fractions: Eight Years Experience with the Alcohol Fractionation Procedure of Nitschmann, Kistler and Leigler," Vox Sang., 1982, Vol. 7, Pgs. 414-424.	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Hope Robinson/	Date Considered	12/22/2008
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